Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Study the prevalence of celiac in epilepsy patients and effect of gluten-free diet in controlling the seizureof the patients

Protocol summary

Summary

Study population are 333 patients with Epilepsy referred from Neurology Clinic of Imam Reza Hospital and Farabi Hospital to Gastroenterology Clinic. At first, patients will be screened for celiac with anti-tTG laboratory test and duodenal biopsy will be performed in positive test patients for final approval. They will be randomly divided into two groups. All of patients will be monitored continuously for 3 months and frequency and duration of seizures will be recorded. Group A (intervention) will receive a gluten-free diet to treat celiac disease and group B (control) will continue normal diet. Patients will be visited monthly till 5 months and frequency and duration of seizures will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108097271N1**
Registration date: **2011-09-01, 1390/06/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2011-09-01, 1390/06/10

Registrant information

Name

Nosratollah Babaii

Name of organization / entity

Kermanshah Univercity of Medical Scinces

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6302

Email address

nbabaii@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah univercity of medical scinces

Expected recruitment start date

2011-06-14, 1390/03/24

Expected recruitment end date

2012-12-14, 1391/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Study the prevalence of celiac in epilepsy patients and effect of gluten-free diet in controlling the seizureof the patients

Public title

Study of celiac frequency in epileptic patient and influnce of celiac treatment on treatment of epilepsy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Epilepsy and getting experience at least one seizure per month during the past six months; confirmed celiac disease with a positive tTG test and duodenal biopsy. Exclusion criteria: Changing the type or dose of anticonvulsant drug in the study period.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size
Target sample size: **333**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Kermanshah university of medical sciences and health services

Street address
Kermanshah university of medical sciences and health services, Shahid beheshti Blvd

City
kermanshah

Postal code
6714858743

Approval date
2011-06-14, 1390/03/24

Ethics committee reference number
12533

Health conditions studied

1

Description of health condition studied
epilepsy

ICD-10 code
G40

ICD-10 code description
epilepsy

2

Description of health condition studied
celiac

ICD-10 code
K90.0

ICD-10 code description
Coeliac disease

Primary outcomes

1

Description
seizure

Timepoint
monthly till 5 month after begining of intervention

Method of measurement
seizures frequency and duration of each seizure

Secondary outcomes

empty

Intervention groups

1

Description
control group: no intervention

Category
N/A

2

Description
intervention group: gluten-free diet

Category
Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center
Neurology Clinic of Imam Reza Hospital and Farabi Hospital Kermanshah.

Full name of responsible person
Dr Nosratollah Babai

Street address

City
Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah university of medical sciences and health services

Full name of responsible person
Dr Fraid Njafi

Street address
Kermanshah university of medical sciences and health services, Shahid beheshti Blvd

City
Kermanshah

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Kermanshah university of medical sciences and health services

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Kermanshah university of medical sciences and health services.

Full name of responsible person
Dr Nosratollah Babai

Position
Resident f inernal medicine

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty